

On the leading edge of women's health

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November 3, 2005

Division of Dockets Management
FDA
DHHS
5630 Fishers Lane
1061
HFA-305
Rockville, MD 20852

**RE: Docket 2005P-0411 Bio-Identical Hormone Replacement Therapy
Citizen Petition**

To Whom It May Concern:

The National Association of Nurse Practitioners in Women's Health (NPWH) strongly believes that the Food and Drug Administration (FDA) should take strong action to protect women's health by launching an investigation into the practices of certain compounding pharmacies that are promoting and distributing misleading and harmful information regarding bio-identical hormone replacement therapy (BHRT) products.

In the wake of all the confusion and concerns caused by the release of the Women's Health Initiative findings, nurse practitioners have witnessed the aggressive promotion of so-called BHRT products to women and health professionals by compounding pharmacies. This marketing effort also includes claims that these products are complete – and safer - substitutes for FDA-approved therapies. In reality, however, no safety or efficacy studies have been conducted on these compounded products. NPWH believes that such widespread, misleading promotion and mass marketing of BHRT steps outside the boundaries of legitimate compounding, and threatens women's health by misinforming clinicians and patients.

Nurse practitioners are at the forefront of counseling women and prescribing therapies for menopausal symptoms. To help these nurse practitioners properly educate their patients, NPWH has produced guidance for clinicians and NPs on counseling women facing decisions about menopausal hormone therapy. We

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have worked hard to provide a balanced perspective on the risks and benefits for hormone therapy.

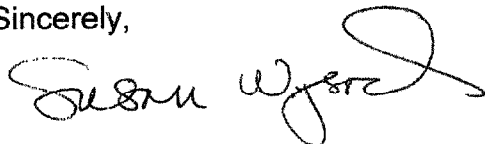
NPWH also worked closely with FDA, other federal agencies, and women's health and health professional organizations to develop FDA's *Menopause & Hormones* Information Campaign. One of the educational components of this campaign is FDA's *Menopause & Hormones* fact sheet, which clearly states, "at this time, we do not know if herbs or other 'natural' products are helpful or safe. Studies are being done to learn about the benefits and risks." The inappropriate and over promotion of the benefits of BHRT is contrary to FDA's own statements about the safety and effectiveness of hormone therapy and should not be allowed to continue.

Therefore, we are deeply disturbed about the mischaracterization of the risks of hormone therapy, and overstatement of the benefits of bio-identical HRT, especially in light of the lack of studies on bio-identical hormone replacement therapy. We are even more disturbed when we hear of sessions at various conferences that repeat these same claims within the context of scientific sessions. The claims made about bio-identical hormones are seductive, if not scientific, for clinicians seeking to help their patients with "alternatives" and for patients seeking relief of menopausal symptoms. We ask that the FDA require that claims about hormones, whether for an FDA approved formulation or a compounded product be the same unless proven otherwise.

While NPWH recognizes and supports legitimate compounding, we believe that the practices of many compounding pharmacies in the promotion and widespread distribution of BHRT products to thousands of women fall outside the definition of legal compounding, and potentially threaten women's health. For this reason, we call on the FDA to conduct an investigation into these practices, take any necessary enforcement action, and act swiftly on the pending Citizen Petition.

Thank you for your consideration of our views.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Wysocki", with a stylized flourish at the end.

Susan Wysocki, RNC, NP, FAANP
President and CEO

cc: FDA Office of Women's Health, Marsha Henderson